Biotech Daily

Monday March 18, 2019

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PROTEOMICS UP 12.5%; KAZIA DOWN 7%**

*** RESAPP DIAGNOSTIC 'BETTER THAN CLINICIANS FOR CROUP'**

*** TELIX WELCOMES EAU PROSTATE CANCER GUIDELINES**

*** ALCIDION $2.1m MIYA, PATIENTRACK, SMARTPAGE UK NHS DEAL**

*** RHYTHM RECRUITS 1st COLOSTAT COLORECTAL CANCER PATIENT**

*** INSIDE DIAGNÓSTICOS TO DISTRIBUTE SIENNA'S HTERT TEST IN BRAZIL**

*** PRANA RECEIVES $3.3m R&D TAX INCENTIVE**

*** TOTAL BRAIN HOPES TO RAISE $7m**

*** GI DYNAMICS $1.4m CRYSTAL AMBER CONVERTIBLE NOTE**

*** MEDIGARD TELLS ASX 'WORKING TO COMPLY WITH RULES'; KT009**

*** AUSTRALIAN ETHICAL TAKES 19.96% OF ANTISENSE**

*** PLATINUM TAKES 8.6% OF ANTISENSE**

*** LEON SERRY, CITY CASTLE, SKED TAKE 6% OF ANTISENSE**

*** CAPITAL GROUP REDUCES TO 6% OF MESOBLAST**

MARKET REPORT

The Australian stock market rose 0.25 percent on Monday March 18, 2019, with the ASX200 up 15.3 points to 6,190.5 points. Sixteen of the Biotech Daily Top 40 stocks were up, 13 fell, eight traded unchanged and three were untraded. All three Big Caps were up.

Proteomics was the best, up four cents or 12.5 percent to 36 cents, with 213,510 shares traded. Mesoblast climbed 10.2 percent; Compumedics was up 7.8 percent; Prana and Uscom were up more than six percent; Antisense improved 5.4 percent; Nanosonics was up 4.1 percent; Benitec and Pro Medicus improved more than three percent; Clinuvel, Cyclopharm, Dimerix, Genetic Signatures, LBT and Volpara rose more than one percent; with Cochlear, CSL, Polynovo and Resmed up by less than one percent.

Kazia led the falls, down four cents or 7.3 percent to 51 cents with 116,873 shares traded. Avita fell 5.3 percent; Orthocell was down 3.6 percent; Immutep, Medical Developments, Opthea and Universal Biosensors shed more than two percent; with Actinogen, Cynata, Ellex, Neuren, Paradigm and Telix down by less than one percent.

RESAPP HEALTH

Resapp says its Smartcough-C-2 trial shows its respirator diagnostic is more accurate than clinicians for the diagnosis of croup and primary upper respiratory tract disease.

Last year, Resapp said it was “very pleased” with the 1251-patient, Smartcough-C-2 results, despite missing the first primary endpoint of the diagnosis or exclusion of pneumonia (BD: Oct 30, 31, 2018).

The company said at that time that results for pneumonia and bronchiolitis were below 70 percent accuracy “and submission for these diseases will occur in a second phase” and it had a “technical issue” with croup results.

Today, Resapp said the pivotal, double-blind, prospective US study was unable to provide croup results “due to a technical issue encountered while providing cough recordings to the clinical adjudicators”.

The company said the croup results were not available in the preliminary results and were delayed until adjudicators listened to all cough recordings and re-reviewed each patient’s medical records.

Resapp said the Resappdx achieved a positive percent agreement, or sensitivity, of 74 percent and a negative percent agreement, or specificity, of 74 percent when compared to a clinical diagnosis for croup.

The company said that analysis of the adjudication data showed that in 52 percent of cases, a final clinical diagnosis of croup required a third adjudicator to resolve disagreement between the first two adjudicators, illustrating the difficulty that even experienced clinicians have in identifying croup.

Resapp said the Resappdx positive percent agreement also exceeded that of the individual treating team clinicians, who saw and treated study participants as part of routine standard of care, who had a 65 percent positive percent agreement when compared to the final adjudicated outcome.

Resapp scientific advisor and principal investigator of the Australian Breathe Easy study Dr Paul Porter said “the accuracy of Resapp’s algorithms for croup is very good, especially when consideration is given to the degree of disagreement observed between adjudicators and the performance of the treating team”.

“Although the high level of disagreement between clinicians for croup in the Smartcough-C-2 study is surprising, we saw only a slightly lower level of disagreement, 40 percent, during the Breathe Easy study, indicating that substantial inter-observer variability clearly exists for croup diagnosis,” Dr Porter said.

Resapp said that two percent of the patient population, or 29 patients, were clinically diagnosed as having croup which resulted in a wide positive percent agreement 95 percent confidence interval.

The company said a larger population would be required to support a US filing for croup.

Resapp chief executive officer Dr Tony Keating said that “the low incidence of croup in the study population demonstrates the relative rarity of croup in this setting and prevents us from including it in our [US Food and Drug Administration] submission, however we are very satisfied with the diagnostic results that we achieved, especially when compared to the treating team’s accuracy”.

Dr Keating said the company expected to file a de novo submission to the FDA this month for lower respiratory tract disease, asthma reactive airways disease and primary upper respiratory tract disease.

“These three indications provide valuable information to clinicians at key decision points and are relevant to every single patient who presents with signs or symptoms of respiratory disease,” Dr Keating said.

Resapp fell 0.3 cents or 3.4 percent to 8.5 cents with 1.9 million shares traded.

TELIX PHARMACEUTICALS

Telix says a European body has published guidelines including prostate-specific membrane antigen positron emission tomography for prostate cancer.
Telix said that the European Association of Urology updated guidelines at its meeting in Barcelona, Spain over the weekend, recommending the use of prostate-specific membrane antigen (PSMA) positron emission tomography (PET) preferentially for the management of recurrent prostate cancer post-prostatectomy.
The company said the recommendations reflected clinical evidence of PSMA imaging compared to existing solutions such as18F-fluciclovine and 18F-fluorocholine.
Telix said the changed guidelines “significantly benefits Telix because it considerably de-risks the pathway for clinical adoption of our prostate imaging product”.
Telix fell one cent or 1.5 percent to 67.5 cents.

ALCIDION GROUP

Alcidion says it has its first Miya Precision, Patientrack and Smartpage installation outside Australia with the UK-based Gravesham National Health Service Trust.
Alcidion said the five-year, $2.1 million contract would deploy Miya Precision with Smartpage and Patientrack in all wards across the Trust’s three hospitals.
The company said it would provide “electronic patient observations, electronic paper charts, clinical assessments, clinical noting, patient flow, bed management and electronic discharge summaries for [general practitioners]”.
Alcidion was up half a cent or 10.4 percent to 5.3 cents with 4.4 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has recruited the first of 1,000 patients in the prospective trial of its Colostat blood test for colorectal cancer detection.
Rhythm said the multi-centre study would comparing the diagnostic effectiveness of Colostat relative to colonoscopy and faecal immunochemical tests (BD: Feb 20, 2019).
The company said it expected to complete the trial by October 2019.
Rhythm fell half a cent or 2.9 percent to 17 cents.

SIENNA CANCER DIAGNOSTICS

Sienna says the São Paulo, Brazil-based Inside Diagnósticos will distribute its human telomerase reverse transcriptase (hTERT) bladder cancer adjunct test in Brazil.
Sienna said Inside Diagnósticos would sell the hTERT test to Brazilian pathology labs as an adjunct to urine cytology.
The company said it would work with Inside Diagnósticos to seek regulatory approval from the Brazilian Health Regulatory Agency (Anvisa).
Sienna was untraded at six cents.

PRANA BIOTECHNOLOGY

Prana says it has received $3,255,130 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Prana said the rebate related to research and development expenditure for the year to June 30, 2018.
Prana was up 0.3 cents or 6.5 percent to 4.9 cents.

TOTAL BRAIN (FORMERLY BRAIN RESOURCE)

Total Brain says it hopes to raise $3.7 million in a private placement, $1.3 million in a conditional placement and $1.9 million in a rights' offer at 2.8 cents a share.
total Brain said the record date for the one-for-eight pro rata non-renounceable entitlement offer was March 21, the offer would open March 26 and close on April 5, 2019.
The company said the funds would be used for software and product development, sales and marketing initiatives and working capital.
Total Brain said it had commitments for the placements and would seek shareholder approval for the conditional placement at its April 29, 2019 extraordinary general meeting.
Total Brain was unchanged at three cents.

GI DYNAMICS

GI Dynamics says it has a $US1 million ($A1,410,100) convertible note and warrant financing with major shareholder Crystal Amber Fund for general working capital.
In its most recent substantial shareholder notice, the London and Guernsey Island-based Crystal Amber said it held 47.47 percent of GI Dynamics (BD: Mar 16, 2018).
Today, GI Dynamics said the new convertible note would satisfy its capital requirements until the end of April 2019 and it would work to extend the March 31, 2019 maturity date of its 2017 convertible note (BD: Jan 20, 2019).
GI Dynamics said Crystal Amber would not be permitted to convert the note into common stock or Chess depositary interests (CDIs) until it had shareholder approval, which would be sought at an extraordinary general meeting.
GI Dynamics was up 0.1 cents or 5.6 percent to 1.9 cents.

MEDIGARD

Medigard says it is working to comply with listing rules 12.1 and 12.2 following the ASX suspending the company from trading earlier this month (BD: Mar 8, 2019).
Medigard said it was working on a development program for KT009 injectable product for degenerative disk disease but would require additional funding.
The company said it "remains positive about the prospects and promise of the KT009 product to treat degenerative disk disease as an injectable biologic product".
Medigard last traded at two cents.

ANTISENSE THERAPEUTICS

Australian Ethical Investment says it has increased its holding in Antisense from 67,333,333 shares (18.12%) to 83,333,333 shares (19.96%).
Australian Ethical said that on March 14, 2019 it bought 1,369,766 shares for $45,202.28 and 18,630,234 shares for $614,797.72 in last week's $1.6 million placement at 3.3 cents a share (BD: Mar 13, 2019).
Antisense was up 0.2 cents or 5.4 percent to 3.9 cents.

ANTISENSE THERAPEUTICS

Platinum Asset Management says it has increased its holding in Antisense from 20,833,333 shares (5.68%) to 35,984,848 shares (8.57%).
The Sydney-based Platinum Asset Management said that it acquired the shares in last week's $1.6 million placement at 3.3 cents a share (BD: Mar 13, 2019).

ANTISENSE THERAPEUTICS

City Castle says it has become a substantial shareholder in Antisense with 25,816,429 shares or 6.15 percent of the company.
The Melbourne-based City Castle said it acquired 7,575,758 shares for $250,000 or 3.3 cents a share, in last week's $1.6 million placement (BD: Mar 13, 2019).
The substantial shareholder notice, signed by Circadian (now Opthea) founder and City Castle director Leon Serry, said that related holders included Sked Pty Ltd Super Fund Account and Traders Macquarie Pty Ltd.

MESOBLAST

The Capital Group says it has reduced its shareholding in Mesoblast from equivalent to 39,627,450 shares (7.95%) to the equivalent to 30,755,583 shares (6.16%)
The Los Angeles, California-based Capital Group said that it reduced its Australian holding from 37,605,700 shares (7.54%) to 28,891,583 shares (5.79%) and its US holding from 404,350 American depository receipts (ADRs) (0.41%) to 372,800 ADRs (0.37%).
The company said that between February 8 and March 14, 2019, it disposed of the shares at an average price of $1.187 a share and disposed of the ADRs at an average price of $US4.307 ($A6.08) a share, with each ADR equivalent to five Australian shares.
Mesoblast was up 13 cents or 10.2 percent to $1.40 with 2.6 million shares traded.